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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re Application of: Geoff J. Clark et al.

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Entitled:

**Compositions And Methods Related To The** Rig Tumor Suppressor Gene And Protein

## INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

#### CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, on July 11, 2002-

Jamès R. Davenport

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following patents are referred to in the body of the specification:

- U.S. Patent No. 4,683,195;
- U.S. Patent No. 4,683,202;
- U.S. Patent No. 4,965,188;

The following printed publications are referred to in the body of the specification:

- ATCC CRL No. 1573;
- ATCC CRL No. 1651;
- ATCC CRL No. 1658;
- ATCC CRL No. 1598;
- ATCC Catalog No. 3363561;

- Amado and Chen (1999) "Lentiviral Vectors the Promise of Gene Therapy Within Reach?" Science 285:674-676;
- Anderson and Young, Quantitative Filter Hybridization, in Nucleic Acid Hybridization [1985];
- Andrejauskas and Moroni (1989) "Reversible abrogation of IL-3 dependence by an inducible H-ras oncogene," EMBO J. 8:2575-2581;
- Ausubel et al. (eds.), Current Protocols in Molecular Biology, Vols. I-IV, John Wiley & Sons, Inc., New York [1994];
- Ausubel et al. (eds.), Current Protocols in Molecular Biology, Ch. 11, John Wiley & Sons, Inc., New York [1994];
- Ausubel et al. (eds.), Current Protocols in Molecular Biology, Vol. 1, pages
   4.9.1-4.9.16, John Wiley & Sons, Inc., New York [1994];
- Ausubel et al. (eds.), Current Protocols in Molecular Biology, Section 15.4,
   "Enzymatic Amplification of RNA by PCR," John Wiley & Sons, Inc., New York [1994];
- Ausubel et al. (eds.) (Current Protocols in Molecular Biology, Section 10.8,
   "Immunoblotting and Immunodetection," John Wiley & Sons, Inc., New York
   [1994];
- Ausubel et al. (eds.), Current Protocols in Molecular Biology, Vol. 4, Section
   A.3F, "Techniques for Mammalian Cell Tissue Culture," John Wiley & Sons,
   Inc., New York [1994];
- Bar-Sagi (2001) "A Ras by Any Other Name," Mol. Cell Biol. 21:1441-1443;
- Bar-Sagi and Feramisco (1985) "Microinjection of the *ras* Oncogene Protein into PC12 Cells Induces Morphological Differentiation," Cell 42:841-848;
- Barbacid (1987) "ras Genes," Annu. Rev. Biochem. 56:779-827;
- Bildirici *et al.* (2000) "Transfection of cells by immunoporation," Nature 405:298;
- Bos (1989) "ras Oncogenes in Human Cancer: A Review," Cancer Res. 49:4682-4689;
- Boshart *et al.* (1985) "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," Cell 41:521;

- Burton *et al.* (1999) "Coexpression of factor VIII heavy and light chain adenoassociated viral vectors produces biologically active protein," Proc. Natl. Acad. Sci. USA 96(22):12725-12730;
- Campbell *et al.* (1998) "Increasing complexity of Ras signaling," Oncogene 17:1395-1413;
- Cavazzana-Calvo et al. (2000) "Gene Therapy of Human Severe Combined
   Immunodeficiency (SCID)-X1 Disease," Science 288:669-672;
- Cepko et al. (1984) "Construction and Applications of a Highly Transmissible
   Murine Retrovirus Shuttle Vector," Cell 37:1053-1062;
- Chen and Faller (1995) "Injection of p21<sup>ras</sup>-generated signals towards cell growth or apoptosis is determined by protein kinase C and Bcl-2," Oncogene 11:1487-1498;
- Chi et al. (1999) "Oncogenic Ras triggers cell suicide through the activation of a caspase-independent cell death program in human cancer cells," Oncogene 18:2281-2290;
- Clark et al. (1993) "Differential antagonism of Ras biological activity by catalytic and Src homology domains of Ras GTPase activation protein," Proc. Natl. Acad. Sci. USA 90:4887-4891;
- Clark et al. (1997) "The Ras-related Protein Rheb Is Farnesylated and Antagonizes Ras Signaling and Transformation," J. Biol. Chem. 272:10608-10615;
- Clark *et al.* (1995) "Biological Assays for Ras Transformation," Methods Enzymol. 255:395-412;
- Clark and Der in *GTPases in Biology*, eds. Dickey and Birmbauer, Springer-Verlag London Ltd., pp. 259-287, 1993;
- Cohen et al. (1972) "Nonchromosomal Antibiotic Resistance in Bacteria:
   Genetic Transformation of Escherichia coli by R-Factor DNA," Proc. Natl.
   Acad. Sci. USA 69: 2110-2114;
- Cole et al. (1985) "The EBV-Hybridoma Technique and Its Application to Human Lung Cancer," in Monoclonal Antibodies and Cancer Therapy, Alan R. Liss, Inc., pp. 77-96;

- Connelly et al. (1998) "Sustained Phenotypic Correction of Murine Hemophilia A by In Vivo Gene Therapy," Blood 91:3273-3281;
- Connelly et al. (1996) "Complete Short-Term Correction of Canine Hemophilia
   B by In Vivo Gene Therapy," Blood 88:3846-3853;
- Coombs, Dictionary of Biotechnology, Stockton Press, New York NY [1994];
- Crowther, "Enzyme-Linked Immunosorbent Assay (ELISA)," in Molecular
   Biomethods Handbook, Rapley et al. [eds.], pp. 595-617, Humana Press, Inc.,
   Totowa, NJ [1998];
- Dijkema *et al.* (1985) "Cloning and expression of the chromosomal immune interferon gene of the rat," EMBO J. 4:761;
- Fabian et al. (1994) "A single amino acid change in Raf-1 inhibits Ras binding and alter Raf-1 function," Proc. Natl. Acad.Sci. USA 91:5982-5986;
- Fiordalisi et al. (2001) "Mammalian Expression Vectors for Ras Family
  Proteins: Generation and Use of Expression Constructs to Analyze Ras Family
  Function," Methods Enzymol. 332:3-36;
- GenBank Accession No. NP\_004666;
- GenBank Accession No. AC006538;
- GenBank Accession No. AAD13119;
- GenBank Accession No. AI497811;
- GenBank Accession No. P10301;
- GenBank Accession No. P10113;
- GenBank Accession No. P01112;
- GenBank Accession No. Q15382;
- GenBank Accession No. TVHUAA;
- GenBank Accession No. XP\_007223;
- Gorman et al. (1982) "The Rous sarcoma virus long terminal repeat is a strong promoter when introduced into a variety of eukaryotic cells by DNA-mediated transfection," Proc. Natl. Acad. Sci. USA 79:6777;
- Graham and van der Eb (1973) "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA," Virol. 52:456;

- Hanahan (1983) "Studies on Transformation of Escherichia coli with Plasmids,"
   Mol. Biol. 166:557-580;
- Harlow and Lane (eds.) Antibodies: A Laboratory Manual, Cold Spring Harbor Laboratory Press [1988];
- Hofmann et al. (1996) "Rapid retroviral delivery of tetracycline-inducible genes in a single autoregulatory cassette," Proc. Natl. Acad. Sci. USA 93(11):5185-5190;
- Huber and Cordingley (1988) "Expression and phenotypic alterations caused by an inducible transforming *ras* oncogene introduced into rat liver epithelial cells," Oncogene 3:245-256;
- Joneson and Bar-Sagi (1999) "Suppression of Ras-Induced Apoptosis by the Rac GTPase," Mol. Cell. Biol. 19:5892-5901;
- Katz and McCormick (1997) "Signal transduction from multiple Ras effectors,"
   Curr. Opin. Genet. Dev. 7:75-79;
- Kauffmann-Zeh *et al.* (1997) "Suppression of c-Myc-induced apoptosis by Ras signalling through PI(3)K and PKB," Nature 385:544-548;
- Kay et al. (2000) "Evidence for gene transfer and expression of factor IX in haemophilia B patients treated with an AAV vector," Nature Genetics 24:257-261;
- Kim *et al.* (1990) "Use of the human clongation factor 1α promoter as a versatile and efficient expression system," Gene 91:217;
- Köhler and Milstein (1975) "Derivation of specific antibody-producing tissue culture and tumor lines by cell fusion," Nature 256:495-497;
- Kozbor *et al.* (1983) "The production of monoclonal antibodies from human lymphocytes," Immunol. Today 4:72;
- Kwok *et al.* (1986) "Retroviral transfer of genes into canine hemopoietic progenitor cells in culture: A model for human gene therapy," Proc. Natl. Acad. Sci. USA 83:4552-4555;
- Laurino et al. (1999) "Monoclonal Antibodies, Antigens and Molecular
   Diagnostics: A Practical Overview," Ann. Clin. Lab Sci. 29(3):158-166;

- Lowy and Willumsen (1993) "Function and Regulation of Ras," Annu. Rev. Biochem. 62:851-891;
- McCormick (1993) "How receptors turn Ras on," Nature 363:15;
- Mahato et al. (1999) "Pharmaceutical Perspectives of Nonviral Gene Therapy,"
   Adv. Genet. 41:95-156;
- Malumbres and Pellicer (1998) "Ras Pathways to Cell Cycle Control and Cell Transformation," Front Biosci 3:d887-d912;
- Maniatis et al. (1987) "Regulation of Inducible and Tissue-Specific Gene Expression," Science 236:1237;
- Maniatis et al.(eds.), Molecular Cloning: A Laboratory Manual, Cold Spring Harbor Laboratory Press, NY, 1982;
- Marshall (1994) "MAP kinase kinase kinase, MAP kinase kinase and MAP kinase," Curr. Opin. Genet. Dev. 4:82-89;
- Mayo et al. (1997) "Requirement of Nf-κB Activation to Suppress p53 Independent Apoptosis Induced by Oncogenic Ras," Science 278:1812-1815;
- Mizushima and Nagata (1990) "pEF-BOS, a powerful mammalian expression vector," Nuc. Acids. Res. 18:5322;
- Morgenstern *et al.* (1990) "Advanced mammalian gene transfer: high titre retroviral vectors with multiple drug selection markers and a complementary helper-free packaging cell line," Nucl. Acids Res. 18:3587-3596;
- Mulcahy *et al.* (1985) "Requirement for *ras* proto-oncogene function during serum-stimulated growth of NIH 3T3 cells," Nature 313:241-243;
- Mullis et al. (eds.) "RT-PCR and Gene Expression," in PCR The Polymerase Chain Reaction, Chapter 24, Birkhauser Publishers, Cambridge, MA (1994);
- Mullis et al. (1986) "Specific Enzymatic Amplification of DNA In Vitro: The Polymerase Chain Reaction," Cold Spring Harbor Symposia, Vol. LI, pp 263-273;
- Feig (1999) "Tools of the trade: use of dominant-inhibitory mutants of Rasfamily GTPases," Nature Cell Biol. 1:E25-E27;
- Nolan and Shatzman (1998) "Expression vectors and delivery systems," Curr.
   Opin. Biotechnol. 9:447-450;

- Ochieng et al. (1991) "Increased Invasive, Chemotactic and Locomotive Abilities of c-Ha-ras-Transformed Human Breast Epithelial Cells," Invasion Metastasis 11:38-47;
- Paterson et al. (1987) "Activated N-ras Controls the Transformed Phenotype of HT1080 Fibrosarcoma Cells," Cell 51:803-812;
- Sambrook et al., Molecular Cloning: A Laboratory Manual, Second Edition, Cold Spring Harbor Laboratory Press, New York (1989), pp 16.7-16.8;
- Sambrook et al., Molecular Cloning: A Laboratory Manual, Second Edition, Cold Spring Harbor Laboratory Press, New York (1989), pp.16.6-16.7;
- Sambrook et al., Molecular Cloning: A Laboratory Manual, Second Edition, Cold Spring Harbor Laboratory Press, New York (1989), at pp.16.9-16.15;
- Sambrook et al. (eds.), Molecular Cloning, Cold Spring Harbor Laboratory
   Press [1989];
- Serrano *et al.* (1997) "Oncogenic *ras* Provokes Premature Cell Senescence Associated with Accumulation of p53 and p16 INK4a," Cell 88:593-602;
- Shirasawa et al. (1993) "Altered Growth of Human Colon Cancer Cell Lines Disrupted at Activated Ki-ras," Science 260:85-88;
- Takiguchi et al. (1992) "NIH3T3 transfectant containing human K-ras
  oncogene shows enhanced metastatic activity after in vivo tumor growth or coculture with fibroblasts," Clin. Exp. Metastasis 10:351-360;
- Trahey et al. (1987) "Biochemical and Biological Properties of the Human N-ras p21 Protein," Mol. Cell Biol. 7:541-544;
- Uetsuki et al. (1989) "Isolation and Characterization of the Human Chromosomal Gene for Polypeptide Chain Elongation Factor-1α," J. Biol. Chem. 264:5791;
- Voss *et al.* (1986) "The roles of enhancers in the regulation of cell-type-specific transcriptional control," Trends Biochem. Sci. 11:287;
- Walker (ed.), *The Protein Protocols Handbook*, Part III, "Blotting and Detection Methods," Humana Press, Totowa, New Jersey [1996];

- Wang *et al.* (1991) "Cell surface receptor for ecotropic murine retroviruses as a basic amino-acid transporter," Nature 352:729-731;
- Yu et al. (1999) "NOEY2 (ARHI), an imprinted putative tumor suppressor gene in ovarian and breast carcinomas," Proc. Natl. Acad. Sci. USA 96:214-219;
- Yuspa *et al.* (1985) "Keratinocytes blocked in phorbol ester-responsive early stage of terminal differentiation by sarcoma viruses," Nature 314:459-462; and
- Zhang (1999) "Development and application of adenoviral vectors for gene therapy of cancer," Cancer Gene Ther. 6(2):113-138.

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- Hengartner (2000) "The biochemistry of apoptosis," Nature 407:770;
- Krammer (2000) "CD95's deadly mission in the immune system," Nature 407:789;
- Nicholson (2000) "From bench to clinic with apoptosis-based therapeutic agents," Nature 407:810-816;
- Vos *et al.* (2000) "Ras Uses the Novel Tumor Suppressor RASSF1 as an Effector to Mediate Apoptosis," J. Biol. Chem. 275:35669;
- Watsuji et al. (1997) "Controlled Gene Expression with a Reverse Tetracycline-Regulated Retroviral Vector (RTRV) System," Biochem. Biophys. Res. Comm.
   234:769; and
- GenBank Accession No. AAD03164.

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This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: July 11, 2002

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